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Flat head syndrome: a child healthcare intervention

Submission date
05/05/2018

Recruitment status
No longer recruiting

Registration date
09/05/2018

Overall study status
Completed

Last Edited
21/06/2019

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and aim of the study
Flat Head Syndrome is a common problem among infants today. The aim of the study is to evaluate the effect of an intervention on prevention and reversal of Flat Head Syndrome.

Who can participate?
All child health nurses employed in January 2012 at child health care centers in the County of Skaraborg Sweden, infants born in the County of Skaraborg Sweden January 2012 - October 2012 and their parents.

What does the study involve?
The intervention is two-armed. First one group of nurses (intervention group) were educated about Flat Head Syndrome and asked to work according to specific guidelines while control group nurses were not. Then newborns were recruited. Parents brought their infants to the child health clinics according the the national schedule and followed their nurses' advice on Flat Head Syndrome. Infants' head shape was judged when infants were at their 2-, 4-, and 12 month well-child visits.

What are the possible benefits and risks of participation?
Benefits of the study include increased knowledge for participating nurses and parents on Flat Head Syndrome prevention and reversal . For individual infants it is possible that participation helps them avoid developing Flat Head Syndrome. Participation does not involve any risks.

Where is the study run from?
The study is run from 26 child health care clinics in the Skaraborg County of Sweden.

When is the study starting and how long is it expected to run for?
The study starts January 1, 2012 and continues until October 31, 2013.

Who is funding the study?
The Skaraborg Institute for Research and Development, R&D Center Primary Health Care Skaraborg, the Local Research and Development Council Skaraborg, and Närhälsan Götene Primary Health Care Clinic.

Who is the main contact?
Freda Lennartsson, PhD student
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Contact information

Type(s)
Scientific

Contact name
Mrs Freda Lennartsson

Contact details
Spjutgatan 5
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10/1029

Study information

Scientific Title
Nonsynostotic plagiocephaly: a child healthcare intervention in Skaraborg County in Sweden

Study objectives
The assumption was that most nonsynostotic plagiocephaly (NSP) can be prevented if child health nurses are educated about NSP and provide parents of infants with early and on-going tailored counseling, and if parents in turn implement recommendations in their infant care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board in Gothenburg, 20/06/2011, Dnr 418-11

Study design
Longitudinal single-blinded interventional study

Primary study design

Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Nonsynostotic plagiocephaly (NSP)

Interventions
All child health nurses employed in the county's child health care centers in January, 2012 were aske to participate in the study. Group assignment was according to clinic: if any nurse at a child health clinic had previous exposure to the project (participated in the pilot study or attended a continuing education group lecture in December 2010), all nurses at that child health care center were placed in the intervention group. Only nurses at child health centers were no nurse had previous exposed to the project were placed in the control group. Infants and parents were placed in the same group as their nurse.
Clinics were randomised to the following interventions:
1. An educational intervention where intervention group nurses were taught about nonsynostotic plagiocephaly.
2. A clinical intervention where child health nurses in the intervention and control groups gave advice to parents of infants on prevention and reversal of nonsynostotic plagiocephaly at well-child visits.
Intervention group nurses were educated in small group sessions or individually at their work place. Sessions took about 1.5 hours for each group of nurses. These sessions were conducted during January 2012.
The duration of the study was 1 year for each infant and parent. Nurses began informing parents about NSP at the first home visit, which takes place when infants are about 1 week old. Cranial head shape of each infant was assessed at their 2-, 4-, and 12-month well-child visit. Infants born in Skaraborg County in February, 2012 and their parents were recruited to the study.
Recruitment period was extended from late January and until there was a sufficient number of infant participants in each group. The last infants were recruited in October 2012.

Intervention Type
Other

Primary outcome measure
Cranial shape of 176 intervention group and 92 control group infants at 2-, 4-, and 12-month visits. Severity Assessment for Plagiocephaly and Severity Assessment for Brachycephaly were used as assessment tools.

Secondary outcome measures

Cranial measurements were taken in order to reliability-test 12-month cranial assessments since the assessment tools have subjective components that increase the variation. Cranial vault asymmetry index (CVAI) was calculated from the two transcranial diagonals, and cranial index (CI) was calculated from the cranial length and cranial width measurements.

Overall study start date
01/01/2012

Completion date
31/10/2013

Eligibility

Key inclusion criteria
1. Child health nurses working in child health centers in Skaraborg County in Sweden in 2012
2. Infants born January-October 2012 in Skaraborg County in Sweden whose parents provided written informed consent
3. Parents of these infants

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
160 intervention group infants and 80 control group infants

Total final enrolment
268

Key exclusion criteria
Did not meet inclusion criteria or consent to participation

Date of first enrolment
01/01/2012

Date of final enrolment
31/10/2012

Locations

Countries of recruitment
Sweden

Study participating centre
Barnavårdscentral Närhälsan Götene Vårdcentral
Torggatan 4
Götene
Sweden
533 34

Study participating centre
25 additional child health care centers in Skaraborg County
Sweden
533 34

Sponsor information

Organisation
The Skaraborg Institute for Research and Development

Sponsor details
Stationsgatan 12
Skövde
Sweden
S-541 30

Sponsor type
Research organisation

Funder(s)

Funder type
Not defined

Funder Name
R&D Center Primary Health Care Skaraborg

Funder Name
The Local Research and Development Council Skaraborg

Funder Name
Närhälsan Götene Primary Health Care Clinic

Results and Publications

Publication and dissemination plan
Planned submission to high-impact peer-reviewed journal by 31/05/2018.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during the current study (birth-related data, cranial asymmetry assessments, cranial measurements) and the analysis will be available to view upon reasonable request by contacting Project Leader Freda Lennartsson, freda.lennartsson@gmail.com. Datasets are coded and participants are not identifiable. However, data will only be shared with researchers interested in plagiocephaly prevention by viewing data together with the project leader, since no consent was obtained from participants to send files containing data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		09/05/2018	02/04/2019	No	Yes
Results article	results	06/02/2019	21/06/2019	Yes	No